

**III. Remarks****A. Status of the Application**

Claims 26-30 and 33-35 are pending. New claims 53-64 that were submitted in the Applicants' previous Response filed June 2, 2008, but were not entered or considered, are not included in the present Response. Claims 26-30 and 33-35 were previously pending. No claims are added, canceled, or amended by the present paper. Reconsideration of this application in light of the following remarks is respectfully requested.

Applicants submit the present paper as a follow up to the Response filed June 2, 2008. In that regard, Applicants' previous Response only addressed the substance of the claim rejections in a cursory manner based on the agreement that was reached between Applicants' representative and the Examiner in the telephone interview of May 20, 2008. In that regard, Applicants respectfully traverse the Examiner's Interview Summary as not accurately reflecting the substance of the telephone interview that occurred on May 20, 2008. It is apparent from the Examiner's Interview Summary and the Advisory Action that the Examiner changed his position regarding the agreement after the interview. It should be noted that Applicants' representative received the Examiner's Interview Summary on June 2, 2008 after filing Applicants' Response earlier that same day. This is why Applicants' Response filed on June 2, 2008 did not fully address the substance of the claim rejections as set forth in the Examiner's Interview Summary despite being filed after the mailing of the Examiner's Interview Summary. With the present paper, however, Applicants more fully address the substance of the claim rejections including the statements made in the Examiner's Interview Summary.

**B. Claim 33**

First, as mentioned in each of Applicants' previous Responses filed February 12, 2008 and June 2, 2008, while the Office Action Summaries indicate that claim 33 is rejected, no rejection of claim 33 is set forth in the Office Actions. The Examiner continues to maintain the rejection of claim 33 without comment, despite the fact that no rejection of claim 33 has been provided. It should be noted that none of the Sava, Gelbard, Burton, or Stalcup patents—cited as the basis for rejecting other pending claims—appear to disclose the use of a hardenable epoxy as required by claim 33. Accordingly, Applicants submit that claim 33 is in condition for allowance.

**C. Claim Rejections – 35 U.S.C. §103**

**1. The Sava and Gelbard Patents**

Claims 26 and 29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of U.S. Patent No. 5,658,286 to Sava (“the Sava patent”) and U.S. Patent No. 5,397,363 to Gelbard (“the Gelbard patent”).

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...

In the present application, a prima facie case of obviousness does not exist for claims 26 and 29 for at least the reasons set forth below.

35 U.S.C. §103(a) provides, in part, that:

“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art . . .”  
(emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated.

With respect to independent claim 26, however, even when combined the Sava and Gelbard patents fail to disclose all of the recited limitations. For example, claim 26 recites “a first support structure, configured to extend through the portals in the first and second bone anchors; a second support structure, configured to be attached to the spine; and a cross bar, which connects the first support structure to the second support structure to form an orthopedic construct; wherein the cross bar is attached to the first and second support structures subcutaneously; and wherein at least the cross bar comprises a media that is hardenable while the support structure is positioned within the body of a patient.” As discussed below, the Sava and Gelbard patents do not disclose such limitations.

As a preliminary matter, Applicants will address this rejection based on the combination of elements as set forth in the Examiner’s Interview Summary mailed May 30, 2008, rather than

any previous statements regarding the combination of elements.<sup>1</sup> In that regard, Applicants understand from the Interview Summary that the Examiner is interpreting the cross links or connecting members 36 of the Gelbard patent to be the first and second “support structures” of claim 29 rather than the “cross bar” of claim 29, and that the Examiner is interpreting the flexible tubing 18 of the Sava patent to be the “cross bar” of claim 29 rather than the first and second “support structures”.

First, it is clear that the flexible tubing 18 of the Sava patent does not meet the recited limitations of the cross bar of claim 26. The tubing 18 is filled with a quick-setting molding material to form “a rigid **temporary master** (Fig. 2C) that is **used as a template** to form the element.” Col. 5, ll. 43-67 (emphasis added). The tubing 18 with the quick-setting molding is not utilized as a spinal support bar. Instead the tubing 18 is simply used as a template for shaping the actual metal spinal support bars that are implanted into the patient. Col. 5, ll. 59-62. Accordingly, the tubing 18 certainly does not connect first and second support structures to form an orthopedic construct as required by claim 26. In that regard, one skilled in the art clearly would not attach the connecting members 36 of the Gelbard patent to the flexible tubing 18 because after the quick-setting material is allowed to cure and harden for several minutes, the tubing 18 is removed and employed as a template for fabrication of a bone fixation element. Col. 4, ll. 25-29. One skilled in the art simply would not use a temporary template for forming a bone fixation element in place of the actual bone fixation element. Thus, for at least this reason a *prima facie* case of obviousness has not been established with respect to claim 26.

With respect to claim 29, which depends from and further limits claim 26, the Sava and Gelbard patents at least fail to disclose “a first cross tie connecting the cross bar to the first support, and a second cross tie connecting the cross bar the second support.” First, the assertion in the Final Office Action that the segmented slotted member 37 can be considered a “cross tie” clearly cannot be supported based on the interpretation of the combination of elements as set forth in the Examiner’s Interview Summary. Specifically, the segmented slotted members 37 are

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<sup>1</sup> For example, in response to Applicant’s arguments submitted February 12, 2008, the Final Office Action mailed April 30, 2008 stated, “The claim also requires a cross bar that attaches to a first and second support structures. Noting the support structures as stated above in Sava, a cross bar (36) connects the first (Gelbard equivalent 28) and second support structure (bone anchors in Gelbard).” This would imply that the cross bar (36) of the Gelbard patent is being considered the “cross bar” of claim 29. However, as the cross bar 36 of the Gelbard patent clearly does not comprise a hardenable media, it cannot be considered the cross bar of claim 29. This understanding of the combination of elements was the basis of the agreement reached between Applicants’ representative and the Examiner in the telephone interview of May 20, 2008 that the rejections were improper.

not utilized in combination with the connecting members 36, which the Examiner is considering the support structures. In that regard, the Gelbard patent states, “Rod support can also be accomplished by top loading, **without a cross link [36]**, by use of the screw attachment 12 to the bone with a segmented slotted member 37.” Accordingly, the segmented slotted members 37 clearly do not connect the cross links or connecting members 36 to the rods 28 because they are not even used with the connecting members 36. Further, the ends 38, 40 of the connecting members 36 cannot be considered the cross ties of claim 29 either. In that regard, claim 26 requires the first support structure to “extend through the portals in the first and second bone anchors.” The Examiner’s Interview Summary states that “at least a portion of the support structures [(cross bars 36)] extend through and connect to the heads and portals of the bone anchor.” The only portions of the cross bars 36 that could be considered to extend through any portion of the bone anchors are the ends 38, 40 that include openings or slots 42, 44. Accordingly, the ends 38, 40 of the connecting members 36 cannot be considered to be the cross ties of claim 29 because then the connecting members 36 would not extend through and connect to the heads and portals of the bone anchor as required by claim 26. Thus, for at least these additional reasons a *prima facie* case of obviousness has not been established with respect to claim 29.

Accordingly, Applicants request that the §103 rejection of claims 26 and 29 over the Sava and Gelbard patents be withdrawn.

## **2. The Sava, Gelbard, and Burton Patents**

Claims 30 and 35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Sava and Gelbard patents as applied to claim 26 in further view of U.S. Patent No. 4,743,260 to Burton (“the Burton patent”). Claims 30 and 35 depend from and further limit claim 26. As shown above, a *prima facie* case of obviousness has not been established with respect to claim 26 with the Sava and Gelbard patents. The Burton patent does not affect this deficiency. Accordingly, for at least the same reasons a *prima facie* case of obviousness has not been established with respect to claims 30 and 35. Therefore, Applicants request that the §103 rejection of claims 30 and 35 over the Sava, Gelbard, and Burton patents be withdrawn.

### 3. The Sava, Gelbard, and Stalcup Patents

Claims 27 and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Sava and Gelbard patents as applied to claim 26 in further view of U.S. Patent No. 6,336,930 to Stalcup et al. ("the Stalcup patent"). Claims 27 and 28 depend from and further limit claim 26. As shown above, a *prima facie* case of obviousness has not been established with respect to claim 26 with the Sava and Gelbard patents. The Stalcup patent does not affect this deficiency. Accordingly, for at least the same reasons a *prima facie* case of obviousness has not been established with respect to claims 27 and 28. Therefore, Applicants request that the §103 rejection of claims 27 and 28 over the Sava, Gelbard, and Stalcup patents be withdrawn.

### IV. Conclusion

It is believed that all matters set forth in the Final Office Action mailed April 30, 2008, the Examiner's Interview Summary mailed May 30, 2008, and the Advisory Action mailed June 23, 2008 have been addressed and that all of the pending claims are in condition for allowance. An indication of allowance of the pending claims is respectfully requested.

Should the Examiner deem that an interview with Applicant's undersigned attorney would expedite consideration of this application, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

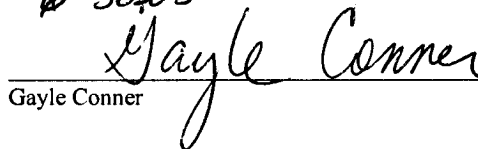
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